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09/809,428	03/16/2001	Baruch Glattstein	1268-121	4916

7590

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EXAMINER
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SIEFKE, SAMUEL P

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 11/04/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/809,428

Applicant(s)

GLATTSTEIN ET AL

Examiner

Samuel P Siefke

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 17-21 is/are rejected.
- 7) ☒ Claim(s) 16 and 22 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or  
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims **1-9,11-15, 21** rejected under 35 U.S.C. 102(e) as being anticipated by Dumitrescu et al. (USPN 6,043,097).

Dumitrescu discloses a reagent package that comprises: a molded casing (casted) having a distinct reaction chamber; two distinct cell adapted for receiving a crushable ampoule and having a flexible pressing area at its outer wall for pressing and crushing an ampoule; an opening between the chamber and a cell is a channel form; a filter to prevent the passage of glass shards from the cell to the chamber (fig.1, #60 being the cell and #72 being the filter); an inlet leading from the outside into the inner space of the reaction chamber for inserting a sample of a tested material; a sample probe having collecting mean at its tip for sampling outer material and delivering it

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through the inlet to the reaction chamber (col. 2, line 9 – col. 3, line 40; col. 4, line 40 – col. 5, line 38; col. 8, lines 27-30; col. 10, lines 27-49; col. 11, lines 10-33)

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim **18** and **19** is rejected under 35 U.S.C. 103(a) as being unpatentable over Dumitrescu et al. (USPN 6,043,097) in view of Matner et al. (USPN 5,418,167).

Dumitrescu discloses a reagent package that comprises: a molded casing (casted) having a distinct reaction chamber; two distinct cell adapted for receiving a crushable ampoule and having a flexible pressing area at its outer wall for pressing and crushing an ampoule; an opening between the chamber and a cell is a channel form; a

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filter to prevent the passage of glass shards from the cell to the chamber; an inlet leading from the outside into the inner space of the reaction chamber for inserting a sample of a tested material; a sample probe having collecting mean at its tip for sampling outer material and delivering it through the inlet to the reaction chamber.

Dumitrescu does not disclose any information regarding the cast molding be of transparent form.

Matner teaches a rapid read-out biological indicator that incorporates a casing that is made from a transparent material in order to allow for a change in color or fluorescence to be visually observed without disassembling the indicator device (col. 14, lines 15-30). Therefore it would have been obvious to one having an ordinary skill in the art at the time the invention was made to modify Dumitrescu to use a transparent material of Matner for the purpose of easily identifying a color change in the indicator device.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dumitrescu et al. (USPN 6,043,097) in view of Brown et al. (USPN 4,732,850).

Dumitrescu discloses a reagent package that comprises: a molded casing (casted) having a distinct reaction chamber; two distinct cell adapted for receiving a crushable ampoule and having a flexible pressing area at its outer wall for pressing and crushing an ampoule; an opening between the chamber and a cell is a channel form; a filter to prevent the passage of glass shards from the cell to the chamber; an inlet leading from the outside into the inner space of the reaction chamber for inserting a

sample of a tested material; a sample probe having collecting mean at its tip for sampling outer material and delivering it through the inlet to the reaction chamber.

Dumitrescu does not disclose any information regarding the use of a fulcrum for reducing the pressure force needed to break the ampoule.

Brown teaches a frangible container with a rupturing device for the sole purpose of reducing the pressure force needed to crush the ampoule (col. 3, lines 3-10). It would have been obvious to one having an ordinary skill in the art at the time the invention was made to modify Dumitrescu to use a fulcrum device of Brown to reduce the pressure needed to crush the ampoule.

Claim **10** is rejected under 35 U.S.C. 103(a) as being unpatentable over Dumitrescu et al. (USPN 6,043,097).

Dumitrescu discloses a reagent package that comprises: a molded casing (casted) having a distinct reaction chamber; two distinct cell adapted for receiving a crushable ampoule and having a flexible pressing area at its outer wall for pressing and crushing an ampoule; an opening between the chamber and a cell is a channel form; a filter to prevent the passage of glass shards from the cell to the chamber; an inlet leading from the outside into the inner space of the reaction chamber for inserting a sample of a tested material; a sample probe having collecting mean at its tip for sampling outer material and delivering it through the inlet to the reaction chamber.

Dumitrescu does not teach a casing wherein the inlet is provided with a one-time-only breakable seal, however it would have been obvious to provide a frangible seal over the sample inlet for reasons of avoiding contamination.

Claim **20** is rejected under 35 U.S.C. 103(a) as being unpatentable over Dumitrescu et al. (USPN 6,043,097).

Dumitrescu discloses a reagent package that comprises: a molded casing (casted) having a distinct reaction chamber; two distinct cell adapted for receiving a crushable ampoule and having a flexible pressing area at its outer wall for pressing and crushing an ampoule; an opening between the chamber and a cell is a channel form; a filter to prevent the passage of glass shards from the cell to the chamber; an inlet leading from the outside into the inner space of the reaction chamber for inserting a sample of a tested material; a sample probe having collecting mean at its tip for sampling outer material and delivering it through the inlet to the reaction chamber.

Dumitrescu does not teach a reagent package comprising a color chart in close proximity to the detection space, however it would have been obvious to provide a color chart in close proximity to the detection space because one could be provided with an immediate comparison of the detection space with the color chart.

#### ***Allowable Subject Matter***

Claim **16** and **22** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 16 would be allowable because no prior art teaches an irreversible interlocking means for a probe and a casing together.

### ***Response to Arguments***

Applicant's arguments filed 7/18/03 have been fully considered but they are not persuasive. Applicant argues "an objective of the present invention is to allow even **unskilled** people to perform the tests." This statement has no bearing because whether or not one needs to be skilled in the art to operate or use a device is not claimed and therefore not commensurate in scope with the instant claims. The applicant argues, "the instant claims call for a distinct reaction chamber, identified by the reference numeral 3 in the drawing of this application. Note that the reaction chamber 3 is empty of material until an ampoule, that is contained in a distinct cell 4, 5, and/or 6 is broken and its contents allowed to proceed through a respective passageway, 4a, 5a and /or 6a from the respective cells 4, 5, and or 6 to the reaction chamber 6." Nowhere does the instant claims mention anything about the reaction chamber being empty until an ampoule is crushed and the reagent is allowed to flow to the reaction chamber. Therefore that statement is moot. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., reaction chamber being empty) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Regarding the distinct reaction chamber. In the last Office action it was argued and described what the Examiner described the reaction chamber in the prior art was, and is noted herein after. "Applicant argues that the prior art does not teach the



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limitations of the claimed "opening which is sufficiently narrow, **or** provided with filtering means". Specifically figure **21** of the prior art discloses a distinct reaction chamber (#16) and an opening between the chamber and the cells. The filter means is the filter screen member 16, which is made of a plastic material and is in the form of a hollow cylinder (col. 5, lines 21-23) and is specifically used for the filtering out any broken glass (col. 3, lines 15-20)." It should be noted that the limitation "opening which is sufficiently narrow, **or** provided with filtering means" can be limited as having either having **one** an opening which is sufficiently narrowed **or** provided with filtering means. Both in each case are provided by the prior art. The ampoule holding cell 28 and 26 have a narrowing of a passage (fig. 11 between the 28 into 34; and 26 into 32), then each distinct reaction chamber have filtering means 16 (which creates the distinct reaction chamber).

Applicant argues, "the examiner has asserted that the '097 reference discloses an inlet leading from the outside to the inner space of the reaction chamber 32 for inserting a sample of a test material. Although the reference's specification and claims have been carefully reviewed, no allegation of a naysuch use has been found."

Examiner would like to point to column 8, lines 27-39 of '097, which recites "when the rocker valves 20 and 22 are in the valve open position such as shown in Fig. 13 fluid can be dispensed into the container chambers 32 and 34 with a dispensing probe 192 (fig. 13)." Clearly this reads on the limitation of inserting a sample into the chamber by use of a sample probe.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel P Siefke whose telephone number is 703-306-0093. The examiner can normally be reached on M-F 7:00am-5:00pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

SPS  
November 3, 2003

A stylized, handwritten signature consisting of several overlapping loops and a horizontal line.

  
Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700